UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

KATHLEEN DONOVAN and PATRICIA CAWLEY, Plaintiffs, - against - PHILIP MORRIS USA, INC., Defendant.	MISC 11-0151 (Pending in the United States District Court for the District of Massachusetts 06-CV-12234 (NG))
BURT XAVIER and JAMES FRANKLIN, Individually and on Behalf of Themselves and All Others Similarly Situated, Plaintiffs, - against - PHILIP MORRIS USA, INC., Defendant.	MISC 11-0152 (Pending in the United States District Court for the Northern District of California C 10-02067 WHA)
CHRISTOPHER GARGANO, and others similarly situated, Plaintiffs, - against - PHILIP MORRIS USA, INC., Defendant.	MISC 11-0153 (Pending in the United States District Court for the Southern District of Florida 1:10-CV-24042-PAS)

AFFIDAVIT OF PAOLO BOFFETTA, M.D.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

KATHLEEN DONOVAN and PATRICIA CAWLEY, Plaintiffs, – against – PHILLIP MORRIS USA, INC., Defendant.	:	Civil Action No. 06 cv 0224-NG (Pending in the District of Massachusetts) **AFFIDAVIT OF PAOLO BOFFETTA IN SUPPORT OF MOTION OF NON-PARTIES TO QUASH SUBPOENAS**

STATE OF NEW YORK)
) ss:
COUNTY OF NEW YORK)

PAOLO BOFFETTA, M.D., being duly sworn, states:

1. I am over the age of eighteen and submit this affidavit in support of the motion of Non-Parties David Yankelevitz, Claudia Henschke, and Mount Sinai School of Medicine (collectively, the "Non-Parties") to quash the subpoenas served upon them by Defendant Phillip Morris USA, Inc. ("PMUSA").

2. Since 2010, I have been a Senior Faculty Member at the Mount Sinai School of Medicine ("MSSM") in Medicine, Hematology and Medical Oncology. I also serve as the Associate Director for Population Sciences of the Tisch Cancer Institute.

3. In addition, I am the Director of the Institute for Translational Epidemiology. The Institute for Translational Epidemiology is an outgrowth of Mount Sinai's well-established community and preventive medicine program. Since Mount Sinai serves one of the most ethnically diverse populations in America, opportunities exist for using epidemiology to study, prevent, and treat diseases. The Institute allows Mount Sinai's epidemiology team to collaborate with investigators from other institutes and departments and makes epidemiological studies a major theme in clinical, translational, and basic research throughout Mount Sinai

4. I am the Scientific Coordinator of the International Lung Cancer Consortium ("ILCCO"). ILCCO is an international consortium of lung cancer researchers, established in 2004 with the aim of sharing comparable data from ongoing lung cancer case-control and cohort studies from different geographical areas and ethnicities. The overall objectives are to achieve greater statistical power, especially for subgroup analyses, reduce duplication of research effort, replicate novel findings, and afford substantial cost savings through large collaborative efforts.

Background and Experience

5. I received a Doctor of Medicine degree in 1982 from the University of Turin. Thereafter, I became a resident at the Second Division of Internal Medicine, and a Research Fellow and Research Assistant at the Cancer Epidemiology Unit of the University of Turin.

6. From 1986 to 1988, I worked as a Research Assistant at the Department of Statistics and Epidemiology of the American Cancer Society in New York.

7. In 1988, I became a Research Assistant at the Division of Epidemiology of the American Health Foundation in New York and a Graduate Research Assistant at the Division of Environmental Sciences at the Division of Health Policy and Management of Columbia University, School of Public Health in New York, where I was awarded a Masters in Public Health in 1989.

8. In 1990, I joined IARC in Lyon, France, first as Medical Officer until 1994 and later as Chief of the Unit of Environmental Cancer Epidemiology (1995–2003).

9. In 2003, I became the head of the Division of Clinical Epidemiology at the German Cancer Research Center in Heidelberg, Germany. In 2004, I rejoined IARC in Lyon to become Group Head and the first Coordinator of the Genetics and Epidemiology Cluster.

10. My main research interests are in molecular epidemiology and cancer prevention. I have published over 700 articles and chapters in medical journals. Over my career, I have held visiting and/or adjunct professorships at the Karolinska Institutet in Stockhom, the University of Heidelberg, the University of Turin, Vanderbilt University, and the Harvard School of Public Health.

CT Screening for Lung Cancer

11. The primary area of scientific debate regarding CT screening for lung cancer relates to the development of evidence of CT screening's benefits sufficient to lead medical societies to draft clinical guidelines recommending CT screening for persons at risk of lung cancer.

12. The data that the International Early Lung Cancer Action Program ("I-ELCAP") has collected and examined, from tens of thousands of individuals at scores of cancer care centers, is not unique. It has been replicated numerous times by others, albeit on smaller scales. The screening protocol by I-ELCAP is published and has been followed by many in the medical profession. There have been scientific criticisms of I-ELCAP, having to do with the methodological approach followed in the I-ELCAP study in terms of whether it is sufficient to prove a benefit of screening.

13. The traditional approach, which is considered the gold standard by virtually all organizations that are responsible for writing clinical guidelines, is the randomized controlled trial, where the group undergoing screening is compared with a group that is not

undergoing the same screening. This was the study design used in the National Lung Screening Trial ("NLST").

14. In contrast to NLST, the approach taken in the I-ELCAP study was not a randomized controlled trial. Instead, the I-ELCAP investigators chose a different approach where they studied how frequently lung cancer could be found in its earliest stage, and how frequently those found with lung cancer were cured, with cure measured by looking at long term survival.

15. The approach taken by I-ELCAP for proving a benefit to screening has not been accepted by many mainstream organizations. While I-ELCAP has collected a large number of cases, the type of evidence they gather is considered an insufficient foundation on which to base clinical guidelines.

16. The approach taken by I-ELCAP has also not been accepted by the medical community at large. The medical community, which has weighed in heavily and clearly in this debate in the medical literature, has stated that the I-ELCAP approach is not sufficient to base policy on because it is subject to various potential biases. Due to the possible biases in the study, it is not generally accepted that the study has adequately demonstrated that screening ultimately saves lives.

17. The type of data that I-ELCAP has produced is not unique. There have been other studies performed in many countries around the world that have shown results similar to I-ELCAP results. This includes studies in Japan, in the United States, and in Europe. Some of these studies published their results before ELCAP, and some are ongoing now. Virtually all of these studies show, to either a slightly greater or slightly smaller extent, the same results as were

shown in I-ELCAP, *i.e.*, that screening leads to more frequent diagnosis of stage I cancer and that persons thus diagnosed have a long survival.

18. However, these findings have not been considered by most medical authorities to demonstrate sufficient benefits such that CT screening should be broadly recommended for long-term smokers.

19. Findings similar to I-ELCAP's findings were also recently reported from a large European randomized controlled trial, known as the NELSON trial. The NELSON investigators reported interim results from their study in the New England Journal of Medicine last year, with the results from the screening arm are similar to I-ELCAP. Significantly, even though the NELSON study reached results similar to I-ELCAP, it will continue until it addresses the traditional endpoint of mortality reduction.

20. The type of data collected and examined by I-ELCAP is available elsewhere, and has been produced from other studies that are now concluded, such as a lung screening trial performed by the Mayo Clinic. The Mayo Clinic data has been made available to other researchers and has been utilized in various other studies such as that performed by Peter B. Bach (and others) and published in the Journal of the American Medical Association. In that publication, although the data showed similar findings as were present in I-ELCAP, the approach taken by the authors to analyze it suggested that screening may not be beneficial.

21. Nevertheless, regardless of whether policy makers find it compelling enough to make a decision about the overall benefit of screening, the data that I-ELCAP has collected and continues to examine is still enormously useful to ongoing research. I-ELCAP provides continuous updates of the screening protocol. The continuing publication of these updates is necessary to: (1) make screening more efficient, and (2) avoid false positives and

unnecessarily invasive and potentially harmful work-ups on patients. Equally important, I-ELCAP also provides information about risk profiles and which patient groups are most likely to benefit.

22. The ongoing I-ELCAP study and its long term collection of information is an invaluable resource for research on early lung cancer. The lead investigators of I-ELCAP have assembled an international team that promotes and encourages world class collaboration, as a result of I-ELCAP's access to cases of early lung cancer that can only be identified in the context of ongoing screening programs.

23. The ILCCO consortium is in the planning phase of developing collaborations with I-ELCAP. Together, a joint ILCCO/I-ELCAP research program would constitute probably the largest lung cancer research collaboration in the world focusing on early lung cancer, including recommending approaches to early diagnosis and treatment.

Adverse Impact of Disclosing I-ELCAP Data to PMUSA

24. Lung cancer, the leading cause of cancer death in the world, represents a global challenge. I-ELCAP is an organization with global reach. A combination of I-ELCAP and ILCCO would join complementary approaches to research, with I-ELCAP focusing more on imaging and ILCCO more on biomarkers and genetics. This combination represents a timely and unique resource in the fight against lung cancer.

25. Were PMUSA's subpoenas to be enforced, it would have the effect of destroying the collaboration between I-ELCAP and ILCCO. No institution in ILCCO would be willing to participate in a collaborative project with I-ELCAP knowing that their data or future research could become the property of PMUSA.

26. Cancer care centers currently contributing data to I-ELCAP, including those that are members of both I-ELCAP and ILCCO, would surely not wish to continue as voluntary collaborators in I-ELCAP, especially those cancer care centers in other countries where the laws regarding access to research are different.

27. In effect, granting PMUSA's subpoenas would have the effect of destroying this global collaboration -- the largest of its type in the world -- focusing on the most deadly of all cancers. Now, with the proven ability of screening to save lives, this surely would be a tragedy on an enormous scale, one with far reaching global consequences.

28. Accordingly, I respectfully request that the Non-Parties' motion to quash the subpoenas served upon them by PMUSA be granted in its entirety.

PAOLO BOFFETTA

Sworn to before me this
28th day of February, 2011

Notary Public

RORY HOGAN, Notary Public
State of New York, No. 01H06153323
Qualified in New York County
Cert. Filed in New York County
Commission Expires 12-21-2014

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